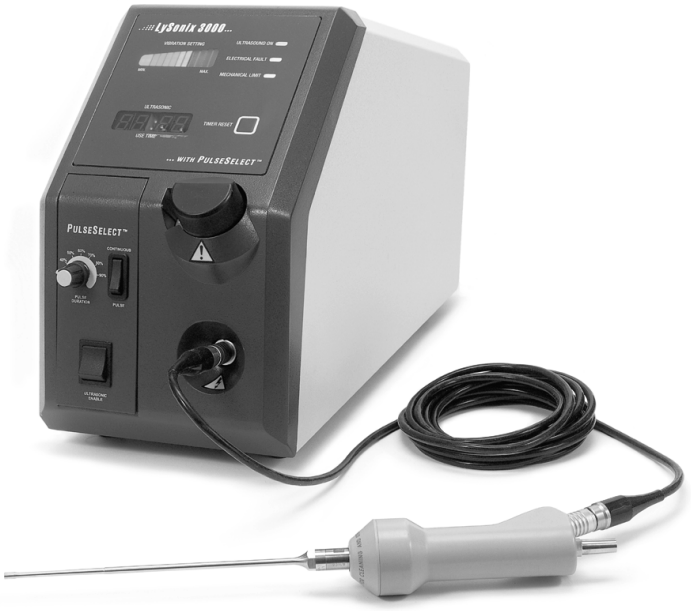
Byron Medical's

LySonix 3000®
with PulseSelect™



Operation Manual

3000G

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Byron Medical, Inc.,
602 West Rillito Street,
Tucson, Arizona 85705

GENERAL SAFETY STATEMENTS

THE LySonix 3000® with PulseSelect™ SHOULD ONLY BE USED BY QUALIFIED MEDICAL PERSONNEL.

THE LySonix 3000® with PulseSelect™ IS AN ELECTRO-MECHANICAL DEVICE THAT, UNDER CERTAIN CIRCUMSTANCES, COULD PRESENT AN ELECTRICAL SHOCK HAZARD TO THE OPERATOR AND/OR PATIENT. PLEASE READ MANUAL THOROUGHLY AND FOLLOW DIRECTIONS STATED HEREIN TO ASSURE MAXIMUM SAFETY DURING OPERATION.

SINCE THE LySonix 3000® with PulseSelect™ IS INTENDED TO BE USED IN VARIOUS TYPES OF INVASIVE SURGERY PROCEDURES, THERE MAY BE INDIRECT DANGER TO THE PATIENT SHOULD THE UNIT FAIL DURING THE PROCEDURE. THEREFORE, IT IS RECOMMENDED THAT A COMPLETE SPARE SYSTEM BE AVAILABLE FOR USE AS A BACKUP.

FCC STATEMENTS

The LySonix 3000® with PulseSelect™ is designed and tested to comply with FCC regulations for conducted and radiated emissions under 21CFR Subchapter J. It also has been designed and tested to comply with EN 60601-1-2:2001 standards for Electrical Emissions and Electrical Immunity.

SAFETY STATEMENTS

The LySonix 3000® with PulseSelect™ has been designed and tested to comply with UL 2601-1 and EN 60601-1 Medical Device Standards with respect to Electrical Shock, Fire and Mechanical Hazards.

Made in the USA

The LySonix 3000® with PulseSelect™ is manufactured wholly in the United States of America.

1. SUMMARY OF SAFETY NOTICES

Please read this section of the manual carefully. It contains a summary of all PRECAUTION, WARNING and CAUTION statements contained in the manual. However, the user is advised to read the entire manual and operate the LySonix 3000® with PulseSelect™ only in accordance with all of the instructions contained herein.

Servicing of the device should only be performed by qualified technicians. Please contact Byron Medical, Inc. There are no service controls accessible to the user.

CAUTION:	**ALL REUSABLE COMPONENTS OF THE DEVICE MUST BE CLEANED AND STERILIZED AND ALL DISPOSABLE COMPONENTS REPLACED BEFORE USING THE DEVICE SYSTEM ON ANOTHER PATIENT.**
CAUTION:	**USE OF CONTROLS OR ADJUSTMENTS OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED HEREIN MAY RESULT IN HAZARDOUS EXPOSURE TO ULTRASONIC ENERGY.**
WARNING:	**TO AVOID ELECTRIC SHOCK, DO NOT REMOVE THE CASE COVER FROM THE GENERATOR, HANDPIECE, IRRIGATION, OR ASPIRATION PUMP UNIT. THERE ARE NO USER SERVICEABLE PARTS INSIDE ANY OF THESE DEVICES.**
WARNING:	**DO NOT ENCLOSE THE ENTIRE GENERATOR HOUSING, IRRIGATION UNIT HOUSING OR ASPIRATION UNIT HOUSING IN A BAG, OR DRAPE WHILE THEY ARE IN OPERATION. AIRFLOW MUST CIRCULATE THROUGH UNITS DURING USE FOR PROPER COOLING OF ELECTRONIC COMPONENTS.**
WARNING:	**CARE MUST BE TAKEN NOT TO DAMAGE THE PROBE. DO NOT GOUGE, KNICK, SCRATCH, BEND OR KINK PROBES DURING USE OR CLEANING/STERILIZING. DISCARD ANY PROBES WHICH SHOW SIGNS OF SUCH DAMAGE.**
WARNING:	**WHEN ULTRASOUND OUTPUT POWER IS ON, DO NOT TOUCH THE PROBE. DOING SO MAY RESULT IN INJURY. PLACE PROBE IN WATER BEFORE ACTIVATING. DO NOT ALLOW PROBE TO RUN UNLESS IMMERSED IN WATER.**
WARNING:	**IF ELECTRICAL FAULT INDICATOR ILLUMINATES AND/OR AN ELECTRICAL FAULT AUDIBLE ALARM SOUNDS, IMMEDIATELY SUSPEND OPERATION. TURN MAIN POWER SWITCH (REAR PANEL OF GENERATOR) TO THE OFF POSITION AND REMOVE PROBE FROM SURGICAL SITE. DO NOT TOUCH METALLIC PARTS OF HANDPIECE, PROBE OR GENERATOR WHILE FAULT IS INDICATED.**

WARNING:	**IF THE PROBE HAS BEEN USED IN A SURGICAL SITE DO NOT ACTIVATE THE ULTRASONICS WITH THE PROBE IN OPEN AIR WITHOUT FIRST WIPING THE PROBE LENGTH WITH A *STERILE WIPE* TO REMOVE BODY FLUIDS.**
CAUTION:	**THE DISPOSABLE ITEMS ARE INTENDED FOR ONE PROCEDURE ONLY. DO NOT ATTEMPT TO REUSE OR RESTERILIZE.**
CAUTION:	**ALL PROBES, HANDPIECES, HANDPIECE CABLES, WRENCHES AND ACCESSORIES ARE SUPPLIED INDUSTRIALLY CLEANED, BUT NONSTERILE. ALL ITEMS INTENDED FOR USE IN THE STERILE FIELD MUST BE CLEANED AND STERILIZED BEFORE FIRST USE AND BEFORE EVERY SUBSEQUENT USE.**
CAUTION:	**DO NOT IMMERSE GENERATOR, IRRIGATION UNIT (IF SUPPLIED) OR THE ASPIRATION UNIT (IF SUPPLIED). THESE UNITS ARE NOT SEALED AGAINST LIQUIDS AND DAMAGE TO EQUIPMENT MAY RESULT.**
CAUTION:	**ENSURE ALL CONNECTIONS AND MATING SURFACES ARE CLEAN AND DRY BEFORE ASSEMBLY.**
CAUTION:	**DO NOT USE THE PROBE OR REDUCED-DIAMETER SECTION OF THE HANDPIECE AS A HAND GRIP. IT IS NOT MADE FOR THIS PURPOSE AND MAY BREAK. HOLD THE MAIN BODY OF THE HANDPIECE ONLY.**
CAUTION:	**THE GENERATOR SHOULD NOT BE TURNED ON UNTIL THE CABLE HAS BEEN CONNECTED TO BOTH THE GENERATOR AND HANDPIECE. OTHERWISE, DAMAGE TO THE GENERATOR CAN RESULT.**
CAUTION:	**DO NOT APPLY EXCESSIVE PHYSICAL FORCE WHEN MANIPULATING THE HANDPIECE PROBE ASSEMBLY IN THE TISSUE. DO NOT FORCE THE PROBE THROUGH THE ANATOMIC AREA.**
WARNING:	**IF AFTER FUSE REPLACEMENT THE FUSE FAILS WHEN THE GENERATOR IS REACTIVATED, DISCONTINUE USE OF THE DEVICE AND CONTACT BYRON MEDICAL INC, IMMEDIATELY. (800-777-3434 or 520-573-0857)**
CAUTION:	**USE *ONLY* GENUINE REPLACEMENT PARTS FURNISHED BY BYRON MEDICAL INC. USE OF PARTS FURNISHED BY OTHER SOURCES MAY RESULT IN DANGER OR FAILURE AND WILL VOID ANY WARRANTY THAT MAY APPLY.**

WARNING:	**PLUGGING GENERATOR UNIT INTO SOCKET WHICH SUPPLIES IMPROPER VOLTAGE MAY CAUSE GENERATOR TO MALFUNCTION OR CREATE A SHOCK OR FIRE HAZARD. BE CERTAIN LINE INPUT VOLTAGE SELECTOR SWITCH IS PROPERLY ADJUSTED.**
WARNING:	**PROPER SYSTEM GROUNDING CANNOT BE INSURED UNLESS UNIT IS CONNECTED TO A PROPERLY WIRED HOSPITAL GRADE OUTLET.**
CAUTION:	**DO NOT PLACE GENERATOR ON TOWEL, FOAM OR OTHER SOFT SURFACE SINCE THE MATERIAL MAY BLOCK AIR VENTS LOCATED ON THE BOTTOM OF THE GENERATOR. BLOCKING THESE VENTS MAY CAUSE GENERATOR TO OVERHEAT AND MALFUNCTION OR CREATE A SHOCK HAZARD.**
CAUTION:	**SYSTEM TEST SHOULD ALWAYS BE DONE IN ADVANCE OF PREPPING PATIENT FOR SURGERY TO MINIMIZE RISK TO PATIENT IN CASE OF SYSTEM MALFUNCTION.**
WARNING:	**IF PROBE IS CRACKED, DAMAGED, OR IN NEED OF REPLACEMENT, SURFACE TEMPERATURE CAN BECOME VERY HOT, SO THAT PROBE MAY PRESENT A BURN HAZARD TO PATIENT OR CLINICIAN, IF TOUCHED. EXERCISE CARE IN TESTING AND HANDLING OF PROBES AT ALL TIMES. PROBES SHOULD BE TESTED FOR TEMPERATURE RISE AT VARIOUS INTERVALS DURING PROCEDURE TO PREVENT BURNING OF PATIENT DUE TO DAMAGED OR CRACKED PROBE. DO NOT TOUCH PROBE WHILE IT IS ACTIVATED.**
WARNING:	**DO NOT HOLD PROBE TIP UP TO EAR. THE OPERATING FREQUENCY OF THE SYSTEM IS ABOVE THE RANGE OF HUMAN HEARING, BUT DOES EMIT ACOUSTIC ENERGY. DO NOT ACTIVATE THE PROBE IN OPEN AIR WITHIN 2 FEET OF THE EARS OF OPERATING ROOM STAFF OR PATIENT.**
CAUTION:	**DURING CLEANING BE CERTAIN TO CLEAR DEBRIS FROM ALL HOLLOW PROBE AND HANDPIECE INTERNAL PASSAGES BY BRUSHING. FAILURE TO DO SO MAY HINDER STERILIZATION OF UNITS DURING AUTOCLAVING.**
CAUTION:	**DO NOT USE ULTRASONIC CLEANERS TO CLEAN HANDPIECE CABLES OR PROBES. USE MANUAL CLEANING TECHNIQUES ONLY.**

CAUTION:	**BEFORE USING LOOSE PACKING MATERIALS, SUCH AS FOAM PELLETS, SHREDDED PAPER, OR EXCELSIOR, BE SURE TO WRAP THE COMPONENT(S) SEPARATELY IN PLASTIC BAGS OR FILM OR OTHER PROTECTIVE WRAPPING.**

Electromagnetic Compatibility Guidance (in accordance with EN/IEC 60601-1-2:2001)

CAUTION:	**THE LYSONIX 3000® WITH PULSESELECT™ IS CONSIDERED MEDICAL ELECTRICAL EQUIPMENT. MEDICAL ELECTRICAL EQUIPMENT NEEDS SPECIAL PRECAUTIONS REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC) AND NEEDS TO BE INSTALLED AND PUT INTO SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THIS OPERATOR'S MANUAL.**
CAUTION:	**PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT CAN EFFECT MEDICAL ELECTRICAL EQUIPMENT.**
WARNING	**THE USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED, WITH THE EXCEPTION OF TRANSDUCERS AND CABLES SOLD BY THE MANUFACTURER OF THE LYSONIX 3000® WITH PULSESELECT™ AS REPLACEMENT PARTS FOR INTERNAL COMPONENTS, MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE LYSONIX 3000® WITH PULSESELECT™.**
WARNING:	**THE LYSONIX 3000® WITH PULSESELECT™ SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT AND THAT IF ADJACENT OR STACKED USE IS NECESSARY, THE LYSONIX 3000® WITH PULSESELECT™ SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.**

List of cables, transducers and accessories:

Item	Cable Length	Type
Ultrasonic Transducer	NA	NA
Transducer cable	3.8m	shielded 4-conductor
AC Main Power cord	3.6m	unshielded 3-conducter
Foot Switch Cable	4.4m	unshielded 2-conductor
Pump Umbilical Cable	1.5m	unshielded 2-conductor

Guidance and manufacturer's declaration – electromagnetic emissions (Table 201)		
The LySonix 3000® with PulseSelect™ is intended for use in the electromagnetic environment specified below. The customer or the user of the LySonix 3000® with PulseSelect™ should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The LySonix 3000® with PulseSelect™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The LySonix 3000® with PulseSelect™ is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity (Table 202)			
The LySonix 3000® with PulseSelect™ is intended for use in the electromagnetic environment specified below. The customer or the user of the LySonix 3000® with PulseSelect™ should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LySonix 3000® with PulseSelect™ requires continued operation during power mains interruptions, it is recommended that the LySonix 3000® with PulseSelect™ be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity (Table 204)

The LySonix 3000® with PulseSelect™ is intended for use in the electromagnetic environment specified below. The customer or the user of LySonix 3000® with PulseSelect™ should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the LySonix 3000® with PulseSelect™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LySonix 3000® with PulseSelect™ is used exceeds the applicable RF compliance level above, the LySonix 3000® with PulseSelect™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LySonix 3000® with PulseSelect™.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the LySonix 3000® with PulseSelect™ (Table 206)

The LySonix 3000® with PulseSelect™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LySonix 3000® with PulseSelect™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LySonix 3000® with PulseSelect™ as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.37
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2. GENERAL INFORMATION - SYSTEM OVERVIEW

2.1 Description of the System

The LySonix 3000® with PulseSelect™ is a system of electromechanical components designed to ultrasonically fragment and aspirate a broad range of soft tissue. The system includes a Generator that produces a 22.5 kHz electrical signal and feeds that signal via the cable to a piezoelectric crystal stack mounted in the autoclavable Operating Handpiece. The crystal stack converts the electrical signal to mechanical vibration at that same frequency. This ultrasonic vibration is amplified as it traverses the length of the titanium Probe attached to the front of the Operating Handpiece. The Operating Handpiece and Probe have a central aspiration channel for use with an aspiration system to remove fragmented material and waste liquids.

2.2 Concept and Principles of Operation

The LySonix 3000® with PulseSelect™ uses ultrasound, or sound waves for fragmentation of soft tissues. Unlike standard cutting or Opto-Thermal systems, the LySonix 3000® with PulseSelect™ offers precise control of tissue ablation due to the controlled ultrasound field generated. This precise control allows the surgeon to perform traumatic fragmentation and removal of tumors and other biomass with minimal disturbance to surrounding tissue structure.

The LySonix 3000® with PulseSelect™ ultrasonically fragments living and necrotic tissue by a process known as cavitation. Cavitation is basically the formation and collapse of microscopic bubbles which are produced at the tip of the titanium Probe mounted on the Handpiece. The Generator unit (Power Supply) feeds a 22.5kHz (22,500 cycles per second) electrical signal to piezoelectric crystals mounted in the Handpiece. The active elements of the Handpiece then vibrate at that same 22.5 kHz frequency. The vibration is amplified by a titanium Front Driver integral to the Handpiece and further amplified down the Probe (or Horn). The distal end of the Probe (the Radiating Face) vibrates at this high amplitude and at the same frequency. When placed in a liquid, the vibrating probe tip causes microscopic bubbles to grow and then collapse with great energy intensity, thus causing the tissue directly in front of the Probe to be liquefied or fragment.

2.3 Functional Components of the System

2.3.1. Generator

The Generator supplies a 22.5 kHz electrical signal to the Handpiece. A feedback circuit tracks frequency changes in the Probe caused by load and temperature changes, and maintains maximum electrical efficiency at all times.

In addition, the Generator incorporates an automatic gain control that maintains the amplitude selected by the user. As the Probe meets resistance, the Generator will automatically supply greater power (wattage) to the Handpiece, thereby keeping the amplitude constant. This is analogous to cruise control on an automobile, which will maintain the car's speed as the road conditions vary. Amplitude, which is the distance the Probe moves out from rest and back in each cycle, determines the extent of tissue disruption. The Generator has a self-limiting feature that prevents damaging overload. Amplitude Setting is indicated by an LED bar graph display on the front panel.

The PulseSelect™ Feature allows the user to initiate a Pulsed Wave Output as opposed to having a Continuous Wave Output. A rocker switch allows the user to change modes while a rotary knob sets the Pulse Duration of the Pulsed Wave Output.

Main power is controlled by the Main Power switch on the back panel of the Generator. Ultrasonic power is controlled by the Ultrasonic Enable switch on the front panel and by a footswitch connected to the rear panel of the generator.

An elapsed time meter records cumulative ultrasonic on-time during a procedure. A reset button resets the elapsed time meter to zero. A Mechanical Limit Detector may detect breakage along the Probe, Handpiece failure, or system overload. These faults will activate an indicator light and an audible alarm. An Electrical Fault Detector detects an open ground wire and short or break in an output circuit. These faults will activate an indicator light as well as an audible alarm. Both fault alarms will deactivate the ultrasonic output of the generator.

2.3.2. Handpiece

The handle section of the Handpiece houses the piezoelectric crystals that transform the electrical energy from the Generator into mechanical vibration. The Front Driver transmits and amplifies the vibration out of the Handpiece casing. A Probe is attached to the Front Driver by an integral mounting stud. This Probe amplifies the motion and provides the debriding surface of the device. As applications require, various Probe configurations will be used to extend the working length, provide increased amplification of vibration, or for fast removal of tissue. The Handpiece incorporates a provision for aspiration fluid connection. The Handpiece is attached to the Generator by a 12-foot long autoclavable Handpiece Umbilical Cable. Two sizes of Handpieces are available, the Standard Handpiece and the FineLine™ Handpiece.

2.3.3. Probes

Broad range of sizes and lengths for micro and macro tissue removal.

Probes can be used on two Handpieces, standard and micro..

2.3.4. Aspiration Unit (Optional)

An optional basic Aspiration unit or a complete Aspiration and Infiltration Platform may also be ordered for use in the surgical site. An optional Aspiration Unit (Model: PT-ASP-III-110 or 220) includes a vacuum pump, vacuum gauge, and vacuum control to adjust the level of vacuum available at the Probe. A reservoir is attached to the pump via a suction line to collect waste liquid. A filter assembly is provided to protect the pumps and the environment from aerosolized aspirant droplets. The Aspiration units are connected to the Handpiece with sterile disposable flexible tubing that is replaced before each procedure.

A separate ON/OFF switch is provided on the Aspiration units to allow independent use and testing of the aspirating feature of the device.

The liquid reservoirs recommended by Byron Medical, Inc., prevents liquid from being transported to the pump via the suction line.

2.4 Controls and Indicators

The controls and indicators available to the operator of the LySonix 3000® with PulseSelect™ are as follows:

Generator:	Main Power ON/OFF Switch (on rear panel) (LED Readout serves as Pilot Light) Line Input Voltage Selector Switch (on rear panel) Ultrasound Enable ON/OFF Switch Amplitude Control Knob Ultrasound On Indicator Light Mechanical Limit Indicator Light Electrical Fault Indicator Light Ultrasonic Use Timer with Reset Amplitude Setting LED Barograph Display Continuous/Pulse Mode Switch Pulse Duration Control Knob
Aspiration Pump:	Power ON/OFF Switch Vacuum Control Vacuum Gauge
Footswitch(s):	Waterproof and Low Voltage
Control Umbilical Cable:	Connects Generator Footswitch control to Irrigation Unit

Figure 1 - Principles of Operation

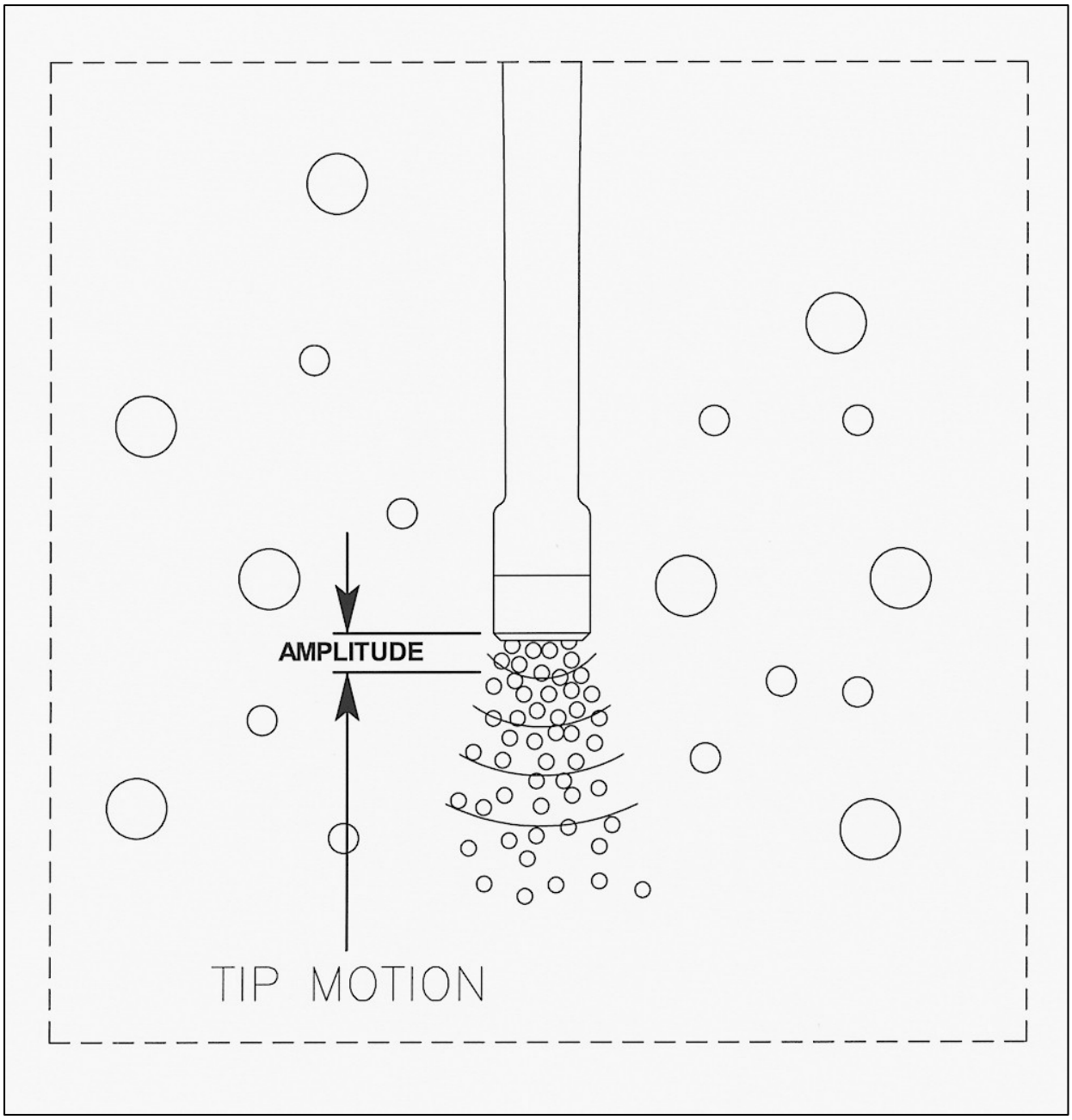


Figure 2 - Handpiece-Probe Assembly

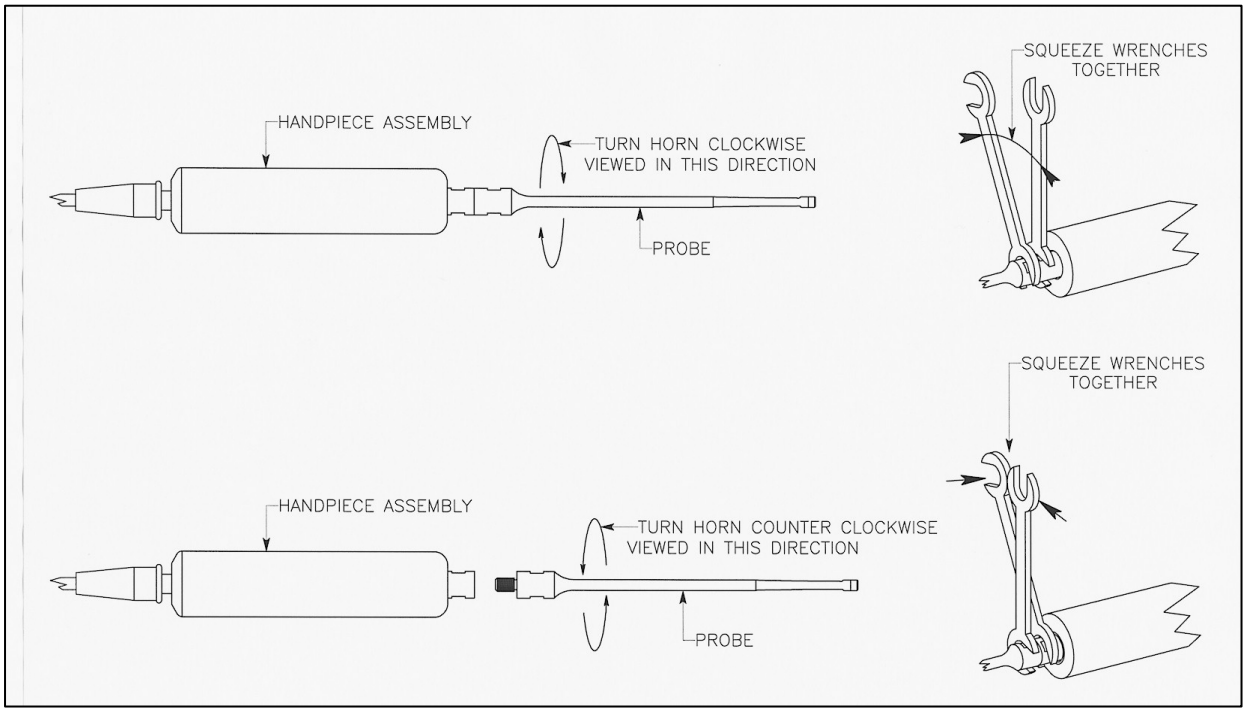


Figure 3 - Front Panel

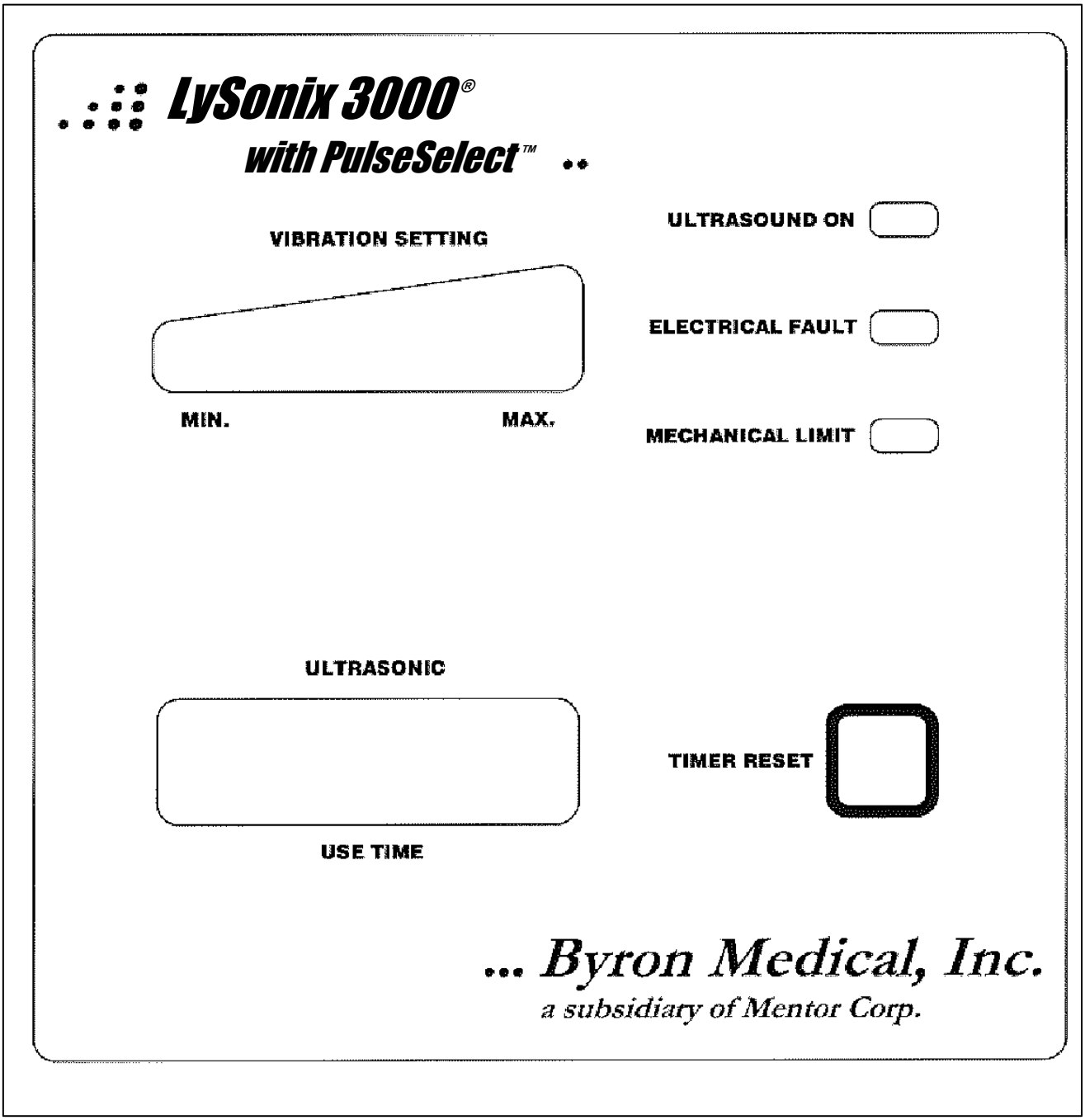


Figure 4 - Rear Panel

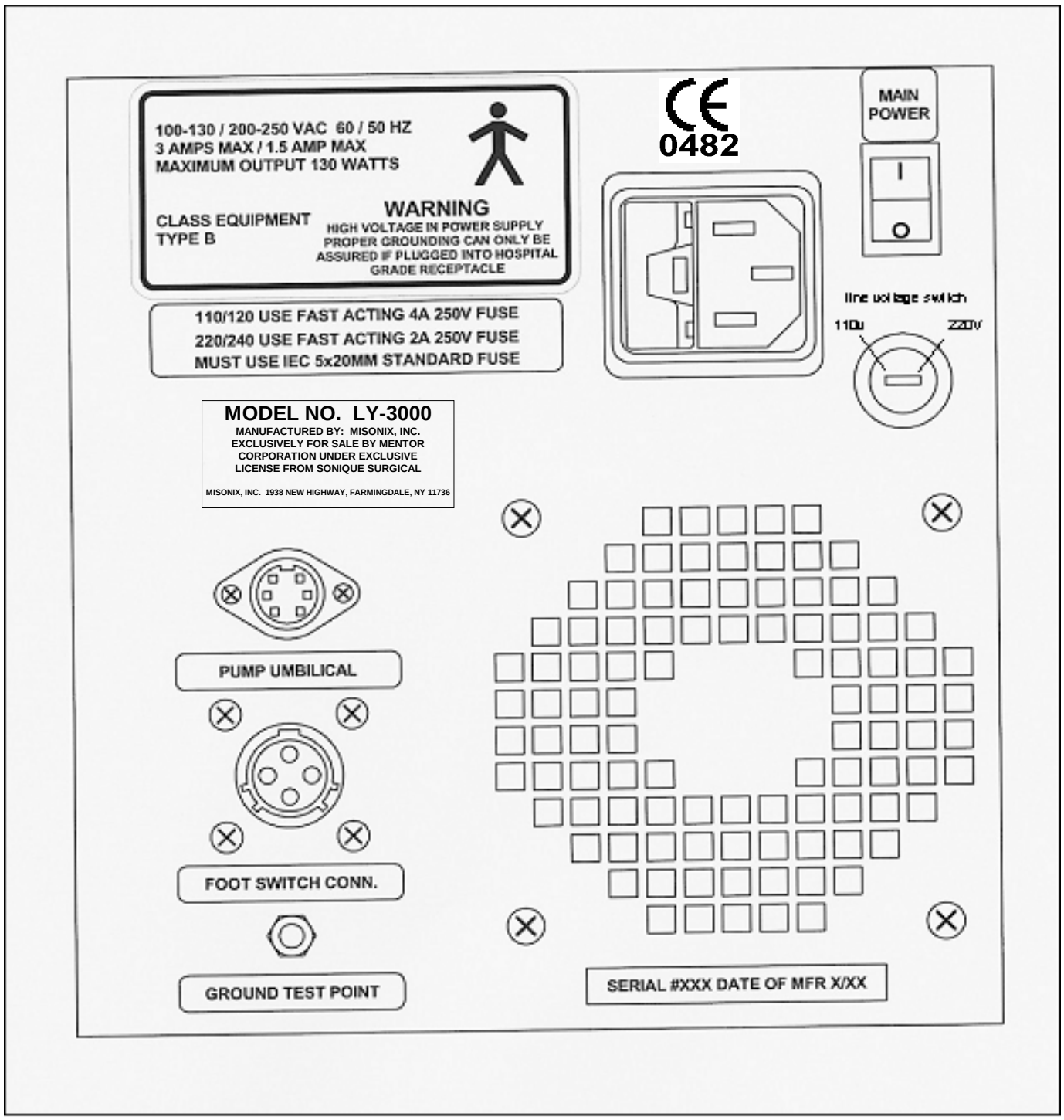
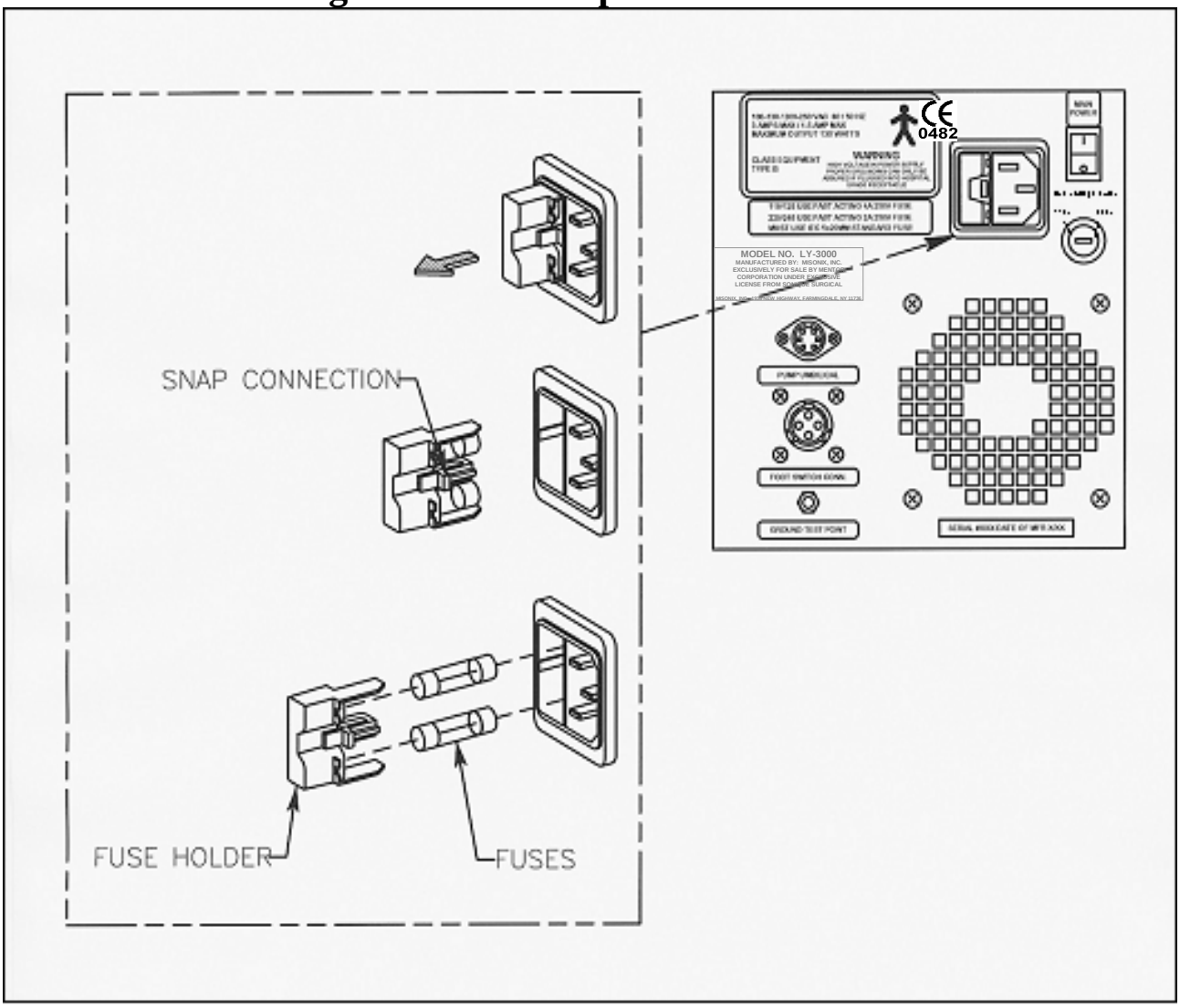


Figure 5 - Explanation of Symbols

SYMBOL	SYMBOL DESCRIPTION
	TYPE-B EQUIPMENT
	DANGEROUS VOLTAGE: CAUTION
	READ INSTRUCTIONS OR REFER TO DOCUMENTATION
	OFF - POWER: DISCONNECTION FROM MAINS
	ON - POWER: CONNECTION FROM MAINS
1PX1	PROTECT AGAINST DRIPPING WATER
	TEST GROUND
	EARTH GROUND POINT

Figure 6 - Fuse Replacement Procedure



- Turn unit OFF and REMOVE power cord from BOTH wall outlet and the Generator.
- Use your thumb to REMOVE the fuse holder below the power cord connector by releasing the spring-loaded snap clips.
- PULL out fuse holder.
- REMOVE and replace with new fuses of the same type. There is no required orientation of the fuses. BE sure to REPLACE BOTH fuses.
- Reinsert the fuse holder by pressing it into the power connector until it snaps into place.
- If the NEW fuse blows, promptly contact Byron Medical, Inc: (800) 777-3434
  (520) 573-0857

2.5 Indications for Use

2.5.1 The LySonix 3000® with PulseSelect™ Ultrasonic Surgical System is indicated for use in the fragmentation and aspiration of soft tissue in the following surgical specialties:

Neurosurgery
Gastrointestinal and Affiliated Organ Surgery
Urological Surgery
Plastic and Reconstructive Surgery
General Surgery
Orthopedic Surgery
Gynecology
External
Condyloma
Benign tumors (lipomas, fibromas, and leiomyomas)
Malignant primary and metastatic tumors of all types and the following cystic lesions:
Bartholin's cysts, Vestibular adenitis, Inclusion cysts and sebaceous cysts.
Abdominal area
Any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus or the supporting structures of the uterus.
Thoracic Surgery
Limited pulmonary resection such as segmetectomies, non-anatomical subsegmentectomies, and metastatectomies.

2.6 Device Specifications

2.6.1 Ultrasonic Generator

Power Input: 110-130VAC 60Hz /200-240V AC 50Hz 250 VA

Operating Frequency: 22.5 kHz ± 500 Hz

Mode of Operation: Continuous Wave or Pulsed Wave (user selectable)

Controls: Amplitude Control
Main Power ON-OFF Switch (rear panel)
Footswitch Control for Ultrasonic Output
Timer Reset
Ultrasonic Enable Switch
Continuous/Pulse Mode Switch
Pulse Duration Setting Knob

2.6.1 Ultrasonic Generator (Continued)

Display Indicators:	Ultrasonic Use Time - digital display Ultrasonic Amplitude Level -LED barograph display Mechanical Limit Indicator - LED Electrical Fault Indicator - LED Ultrasonic On Indicator - LED
Operating Conditions:	Temperature 55-95°F Relative Humidity 20-90% (non condensing)
Dimensions:	7 1/2" W x 19" D x 11" H
Weight:	17 lbs.

2.6.2 Handpiece (Typical)

Operating Frequency:	22.5 kHz ± 150 Hz
Power Capability:	150 Watts
Operating Conditions:	Temperature 55-95°F
Dimensions:	6.75" L (nom) x 2" Dia. (nom)

3. UNPACKING INSTRUCTIONS

Carefully inspect shipping container before opening. After visual inspection of container, carefully unpack all components and place on a table or cart. Visually inspect all components for obvious shipping damage. Retain the shipping container and immediately notify the shipping carrier of any damage

The following components are included:

3.1 Reusables (Non Sterile):

3.1.1. LySonix 3000® with PulseSelect™ System Are Supplied In the Following Configurations

Catalog Number	Description
3000S (includes the following):	3000 S STANDARD SYSTEM
3000G	1 each 3000 Generator
3000HP	2 each 3000 Handpiece
30000CAB	2 each 3000 Cable
2020-50	1 each Footswitch
2010- 55	1 each Power Cord
2020-32	1 each Wrench Set
2010-31	1 each Brush Set for Probes
5610-530	5mm x 30cm Hollow Bullet Tip
5620-420	4mm x 20cm Hollow Golf Tip
5620-530	5mm x 30cm Hollow Golf Tip
2010-30	Probe Tray Autoclavable

Catalog Number	Description
3000 MS (includes the following):	3000 S MICRO SYSTEM
3000G	1 each 3000 generator
3000MHP	Micro Handpiece and cable
2020-50	1 each footswitch
2010- 55	1 each Power Cord
2010-31	1 each Brush Set for Probes
2020-32	1 each Wrench Set
3000M-220BTS	Micro Cannula 2mm x 20cm Solid Bullet Tip
3000M-210BTS	Micro Cannula 2mm x 10cm Solid Bullet Tip
3000M-310BTH	Micro Cannula 3mm x 10cm Hollow Bullet Tip
3000M-3520BTH	Micro Cannula 3.5mm x 20cm Hollow Bullet Tip

CAUTION: Use only genuine replacement parts distributed by Byron Medical, Inc. Use of parts furnished by other sources may result in danger or failure and will void any warranty that may apply.

4. OPERATING INSTRUCTIONS

4.1 System Components Preparation

CAUTION - All Probes, Handpieces, Handpiece cables, wrenches and accessories are supplied industrially cleaned, but non-sterile. All items intended for use in the sterile field must be cleaned and sterilized as per following instructions before first use and every subsequent use.

All the following reusable items must be **cleaned and sterilized** prior to the procedure in accordance with appropriate protocols as provided herein.

HANDPIECES
HANDPIECE FRONT CAPS
PROBES
HANDPIECE CABLES (If removable from Handpiece)
WRENCHES

All the components are steam sterilizable. THESE MUST ALWAYS BE CLEANED AND STERILIZED PRIOR TO USE AND AFTER USE, TO PROTECT CLINICIANS, TECHNICIANS AND PATIENTS DURING ROUTINE HANDLING AND USE.

The front panels of the Generator, Irrigation and/or Aspiration Units may also be covered with clear sterile plastic covers during the procedure.

WARNING – DO NOT enclose the entire generator housing, irrigation unit housing or aspiration unit housing in a bag, or drape while they are in operation. Airflow must circulate through units during use in order for proper cooling of electronic components.

4.1.1 Cleaning and Sterilizing

Refer to Maintenance Section (Section 8.0) for cleaning and sterilizing instructions.

4.2 System Assembly

NOTE: - It is recommended that the Generator Irrigation Unit (if supplied) and Aspiration Unit (if supplied) be positioned on a cart or table outside the sterile field of the Operating Theater. The Generator must be placed on a smooth and level hard surface.

CAUTION: - DO NOT place generator on towel, foam or other soft surface since the material may block air vents located on the bottom of the generator. Blocking these vents may cause generator to overheat and malfunction or create a shock hazard.

4.2.1. Main Power Switch

WARNING: - Plugging generator unit into a socket which supplies improper voltage may cause generator to malfunction or create a shock or fire hazard. Be certain line input voltage selector switch is properly adjusted. Use a small screw driver to move switch to desired setting (110v or 220v) . See Figure 4 Rear Panel

Verify that the Main Power Switch on the rear panel of the Generator and the Ultrasonic Enable Switch on the front panel of the Generator are in the "OFF" position and that the Amplitude Control on the front panel is set at zero. Verify that the Line Input Voltage Selector on rear panel of Generator is set to the proper setting for the line voltage to be supplied by the outlet. Plug the female end of the line cord into the rear of the Generator. Plug other end of line cord into Hospital grade socket receptacle.

WARNING: - Proper system grounding cannot be insured unless unit is connected to a properly wired hospital grade outlet.

CAUTION: - The generator should not be turned on until the Handpiece cable has been connected to both the Generator and Handpiece. Otherwise, damage to the generator may result.

4.2.2 Attaching Footswitch

Attach the plug from the Footswitch into the connector on the rear panel of the Generator. Make certain that connector is fully inserted. Position Footswitch on floor in area easily accessible during procedure.

4.2.3 Handpiece

Handpiece, Handpiece Front Cap, Probes, and Aspiration Tubing (if used) - should be assembled on a tabletop covered with a sterile drape. Only persons authorized to be in sterile field should assemble these components.

4.2.3.1 Front Driver of Handpiece

Thread Probe into Front Driver of Handpiece by hand until tight. Refer to Figure 2. DO NOT force the Probe into the Handpiece threads; it must turn in smoothly all the way until the mating faces touch. Use the two open end wrenches supplied and fit them into the flats on both the Probe and Front Driver of the Handpiece for final tightening. If a two piece Probe is used, attach distal end of Probe to Extender in like manner.

CAUTION: - Ensure all connections and mating surfaces are clean and dry before assembly.

CAUTION: - Use two wrenches at all times. DO NOT attempt to tighten or loosen Probes by holding the Handpiece case. Never apply pipe or strap wrench to the Handpiece case.

WARNING: - Care must be taken not to damage the Probe. DO NOT gouge, knick, scratch, bend or kink Probes during use or cleaning/sterilizing. Discard any Probes that show signs of such damage.

4.2.3.2 Front Cap of Handpiece

Thread on the Handpiece Front Cap. Finger tighten only. DO NOT USE WRENCH OR PLIERS TO TIGHTEN CAP TO HANDPIECE BODY.

4.2.4 Connecting Handpiece Cable to Generator

Attach one end of high frequency Handpiece Cable to output connector on Generator front panel. Line up the red dot on the cable connector with the corresponding line on the front panel connector. Push the cable connector into place. Assure that the connection snaps into place, as indicated when the red markings line up.

4.2.5 Connecting Handpiece Cable to Handpiece (Removable cables Only)

Connect other end of Handpiece Cable to the connector at rear of Handpiece. Assure that connection snaps into place as in the previous step.

4.2.6 Connecting Aspiration Tubing to Handpiece

Connect one end of the sterile aspiration tubing to the rear aspiration port of the Handpiece pushing firmly on the tubing connector and connect the other end of the tubing to the Waste Reservoir of the ASPIRATION UNIT. Set-up and test the unit according to the instructions supplied with that device.

5. SYSTEM TEST

CAUTION - System test should always be done in advance of prepping patient for surgery to minimize risk to patient in case of system malfunction.

5.1 Turn the Main Switch (rear panel) to the ON position. Fan should start and the Ultrasonic Use Timer LED Display should illuminate.

5.2 Turn on the IRRIGATION UNIT (if so equipped).

5.3 Turn on the ASPIRATION UNIT (if so equipped). If hollow Probes are utilized, then suction should be felt at the distal end of the Probe. Placing the distal end of the Probe in sterile saline should result in liquid being evacuated from the container and deposited in the Waste Reservoir. Check all aspirant line connections for leaks and repair or replace as necessary.

WARNING - When ultrasound output power is on DO NOT touch the Probe. Doing so may result in injury. Place Probe in water BEFORE activating. DO NOT allow Probe to run unless immersed in water.

5.4 Place the Ultrasound Enable Switch (front panel) in the ON position, set the Pulse Mode Switch to "CONTINUOUS". Turn the Amplitude Control Knob to setting “5”.

5.5 Depress the Footswitch. The Ultrasound ON Light should illuminate. A Bell type sound should be heard for 1 second upon pressing of the Footswitch. The Ultrasound Use Time readout should count-up in 1 second increments. Placing the distal end of the Probe in sterile liquid should result in an audible hiss or noise and bubbles of liquid should appear below the distal end of the Probe in the liquid.

WARNING - When ultrasound output power is on DO NOT touch the Probe. Doing so may result in injury. Place Probe in water BEFORE activating. DO NOT allow Probe to run unless immersed in water.

WARNING – DO NOT hold Probe tip up to ear. The Operating frequency of the system is above the range of human hearing, but does emit acoustic energy. DO NOT activate the Probe in open air within 2 feet of the ears of operating room staff or patient.

5.6 Release the Footswitch. The Ultrasound output should be disabled. The Ultrasound Use Time indicator should freeze at the last reading. If so, reset timer by pressing and releasing the RESET BUTTON.

5.7 Repeat steps 5.5 through 5.6 two more times to verify operation of system. If performance cannot be verified or if Mechanical Limit Light or Electrical Fault Light illuminates or audible alarm is heard, go to Troubleshooting Chart for instructions. Otherwise, proceed to next step.

5.8 Reset Ultrasound Use Timer by pressing Reset Button momentarily. Depress Footswitch to turn on Ultrasound Output Power. Hold distal end of Probe in air and run system for 30 seconds. Unit should run normally with no visual or audible alarms activated. Running unit for 30 seconds checks Probe for defects and proofs all electrical and mechanical connections.

5.9 Release Footswitch. Gently feel along length of Probe. Probe temperature should not be significantly above ambient temperature, regardless of how long it was operating. If Probe feels hot at the junction of the Handpiece and Probe, retighten with wrenches supplied and retest. If Probe feels hot at any point along its length, replace Probe and retest.

WARNING - If Probe is cracked, damaged, or in need of replacement, surface temperature can become very hot, so that Probe may present a burn hazard to patient or clinician, if touched. Exercise care in testing and handling of Probes at all times. Probes should be tested for temperature rise at various intervals during procedure to prevent burning of patient due to damaged or cracked Probe. DO NOT touch Probe while it is activated.

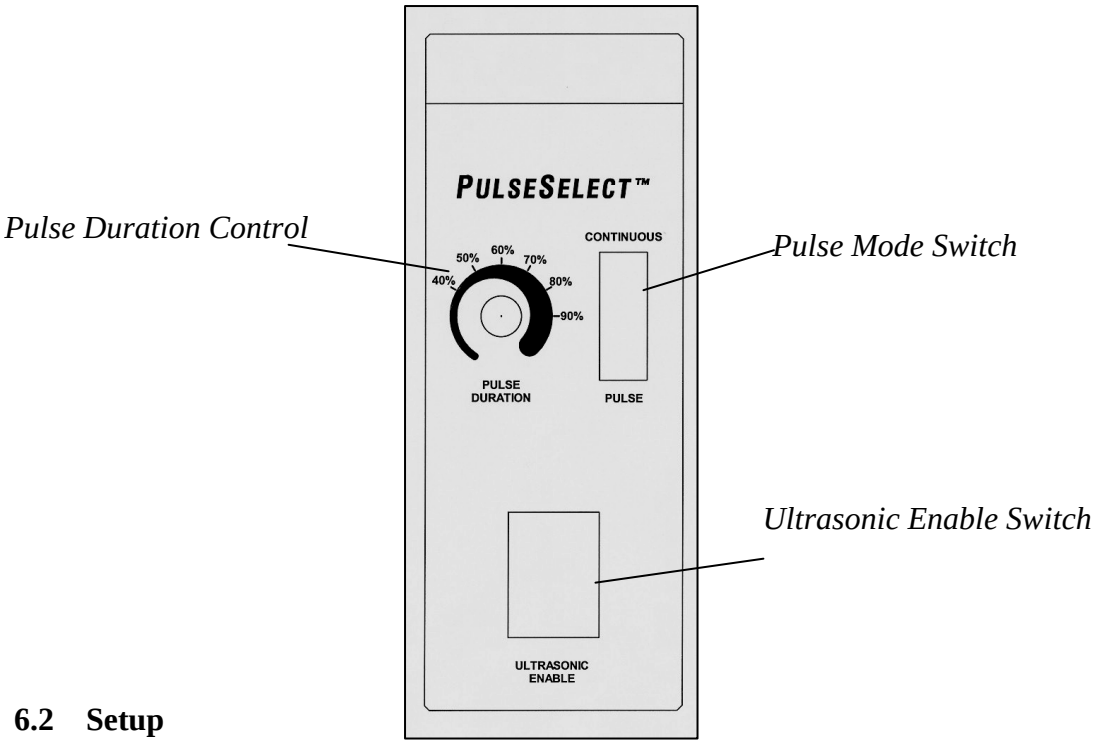
5.10 Refer to the Instruction Sheet Supplied with the Probe. Note the **maximum** value of Amplitude Setting allowed for the Probe in use. **DO NOT** exceed this value at any time during testing or actual use with the Probe.

5.11 Refer to Section 6 for Instructions on the PulseSelect™ Feature.

LySonix 3000® with PulseSelect™ SYSTEM IS NOW READY FOR USE.

6. INSTRUCTIONS FOR PULSESELECT™ FEATURE

6.1 Explanation of Front Panel with PulseSelect™ Feature



6.2 Setup

6.2.1 Verify that the Pulse Mode Switch is in the "CONTINUOUS" position. Verify that the Pulse Duration Control at the front panel is set to the minimum position (fully counter clockwise).

6.2.2 Attach the Handpiece cable to the corresponding connector. Align markings and push the cable connector in place. Assure that the connection snaps into place.

6.3 System Test

6.3.1 Perform system test as follows:

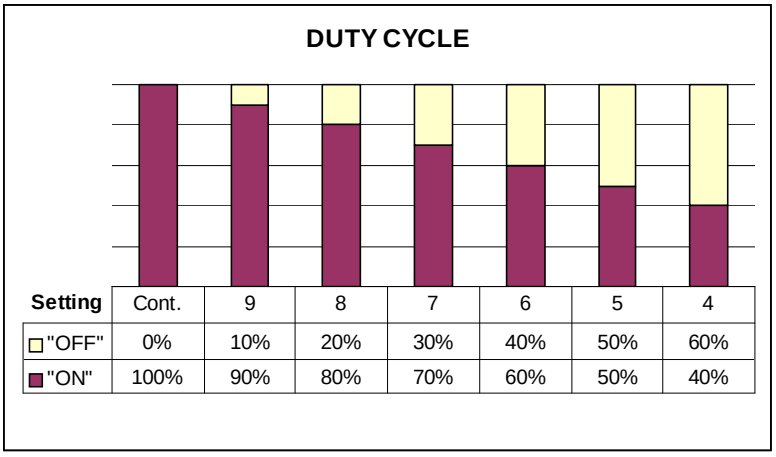
6.3.2 Flip the Pulse Mode Switch to the "PULSE" position.

6.3.3 Depress the Footswitch as described in the user's manual. The ultrasound light shall illuminate and shall be flashing. A Bell type sound should be heard for 1 second upon pressing of the Footswitch. The Ultrasound Use Time readout shall count-up in 1 second increments. (Note that the Ultrasound Use Time will indicate the duration of time the Footswitch is being depressed when the "Continuous" feature is selected).

6.4 Selection of Pulse Duration

6.4.1 Verify that the Pulse Mode Switch is in the "PULSE" position.

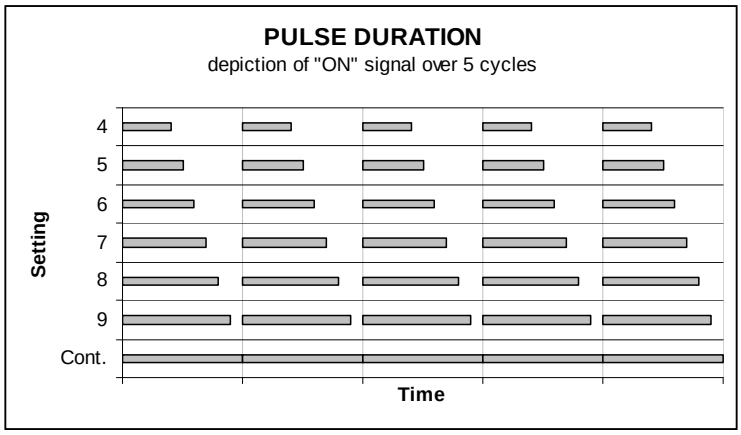
6.4.2 The following figure will present an overview of the available Pulse cycles. The Pulse cycle (also referred to as Duty cycle) is divided into an ON period and an OFF period. Variations of this relationship are described below.



Setting	Cont.	9	8	7	6	5	4
"OFF"	0%	10%	20%	30%	40%	50%	60%
"ON"	100%	90%	80%	70%	60%	50%	40%

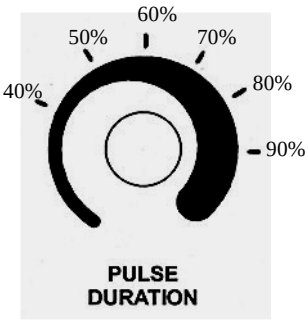
The energy input is reduced by switching between "ON" and "OFF" periods. For example, at setting "4" the energy input is reduced by 60% compared to 100% at continuous mode.

6.4.3 The figure below exhibits variations of the pulse duration over the same the time-period.



Note that the individual cycle remains the same while the "ON" and "OFF" periods are varied.

6.5 Pulse Settings



(**Settings illustration**)

Pulse settings 40% to 90% are determined by rotating the Pulse Duration Control. Detents spaced approximately 30 degrees apart predetermine these settings. Minimum setting or setting "40%" is with the Pulse Duration Control knob in full counter clockwise position. Maximum setting or setting "90%"is with the Pulse Duration Control knob in full clockwise position.

6.5.1 Set the Pulse Duration Control Knob to the desired setting.

6.5.2 Depress Footswitch and verify that the Ultrasound Output is pulsing and not continuous.

NOTE -The timer will only Increment when the ultrasound output is ON and will NOT advance when the output is OFF regardless if the Footswitch is being continuously depressed.

6.5.3 Release the Footswitch, disengage the Ultrasound Enable Switch and place the Handpiece/Probe on a sterile drape.

LySonix 3000® with PulseSelect™ SYSTEM IS NOW READY FOR USE.

7. SYSTEM TROUBLESHOOTING

7.1 Troubleshooting Guide (Symptom, Possible Cause, and Remedial Action)

WARNING - To avoid electric shock, DO NOT remove the case cover from the Generator, Handpiece, irrigation or aspiration pump units. There are no user serviceable parts inside any of these devices.

CAUTION – Do not apply excessive physical force when manipulating the Handpiece Probe assembly in the tissue. Do not force the Probe through the anatomic area.

WARNING - If electrical fault indicator illuminates, suspend operation immediately. Remove Probe from patient. DO NOT touch metallic parts of Handpiece, Probe or Generator.

SYMPTOM	POSSIBLE CAUSE	REMEDIAL ACTION
System does not turn on	Power cord not connected	Check power cord
	Power outlet off	Check wall socket for voltage
	Blown line fuse(s)	Replace fuse(s)
Mechanical limit light illuminated and pulsing audible alarm activated.	Loose Probe to Handpiece connection	Retighten Probe to Handpiece.
	Cracked, damaged, or broken Probes.	Replace Probe.
	Power overload condition at Probe tip.	Release pressure on Probe.
	Overheated Probe.	Cool Probe. Retest. If Probe heats, replace.
	Clogged Probe or Handpiece.	Use brush set to clear debris from Probe/ Handpiece.
	Handpiece malfunction or defective.	Replace Handpiece.
Electrical fault light illuminated and steady audible alarm activated.	Handpiece and/or cable disconnected.	Check all electrical connections.
	Faulty cable or Handpiece.	Replace cable or Handpiece.
	Faulty Generator.	Replace Generator.

7.2 Mechanical Limit Alarm Reset

7.2.1 Release Footswitch.

7.2.2 Depress Footswitch again. If Mechanical Limit Light and Audible Alarm sounds, refer to Troubleshooting Guide.

7.3 Electrical Fault Alarm Reset

7.3.1 Switch ULTRASOUND ENABLE switch OFF.

7.3.2 Flip MAIN POWER switch OFF. Refer to Troubleshooting Guide and go through ALL steps given.

7.3.3 Flip MAIN POWER switch ON and then ULTRASOUND ENABLE switch ON.

7.3.4 Depress Footswitch. If Electrical Fault Alarm activates again, **DISCONTINUE USE, REPLACE ENTIRE SYSTEM WITH BACKUP, SET UP AND TEST BACKUP** and continue operation. Call Byron Medical Inc., for further instructions.

8. SYSTEM DISASSEMBLY AND MAINTENANCE

8.1 Cleaning and Sterilization

CAUTION - All Probes, Handpieces, Handpiece Cables, Wrenches and accessories are supplied industrially clean, but non-sterile. All items intended for use in the sterile field must be cleaned and sterilized as per the following instructions before first use and before every subsequent use**.**

8.1.1 Follow ANSI/AAMI ST35, Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Devices (1991) or latest edition, or such other guidelines as may be directed by Hospital or Clinic GHP's.

8.1.2 Disassemble all components of system in reverse order of assembly (refer to Figure 2), including the Probe from the Handpiece, the Front Cap from the Handpiece and the tubing from the Handpiece, and the Irrigation and/or Aspiration Unit. Unplug all power cords. Use Wrenches supplied and rotate wrenches as shown in Figure 3 to untighten Probes from Handpiece. Separate Probes from Handpiece.

8.1.3 Dispose of all flexible tubing (but NOT the Handpiece Cable if detachable) and the Waste Reservoir Container in accordance with standard hospital procedures for disposal of contaminated biological wastes.

8.1.4 Rinse the Probes, Wrenches and Handpiece under warm running water. **Handpiece should not be immersed fully under water.**

8.1.5 Brush hole in Handpiece and Hollow Probes using the brushes as follows:

Item To Be Cleaned	**Brush**
3.5mm Diameter Probe	Small Cleaning Brush-Probe
4mm Diameter Probe	Small Cleaning Brush-Probe
5mm Diameter Probe	Small Cleaning Brush-Probe
Handpiece	Large Cleaning Brush-Handpiece

8.1.6 Brushing should be done with anti-microbial and anti-viral soap and warm running water. This insures clearing of debris from the internal passages. Rotate brush as it is inserted to help clear debris and stains. Brushes should be inserted fully through the unit. Repeat this procedure at least four (4) times. A standard soft bristle cleaning brush may be used to scrub exterior surfaces of Handpiece, Front Cap and Probes. Rinse all soap residue from interior and exterior of unit under warm running water for a minimum of 1 minute. **Handpiece should not be immersed fully under liquid.**

CAUTION: - Be certain to clear debris from all Hollow Probes and Handpiece internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving.

CAUTION: - **DO NOT** use ultrasonic cleaners to clean Handpieces Cables or Probes. Use manual-cleaning techniques only.

8.1.7. Wash wrenches under warm water mixed with anti-microbial and anti-viral soap. Wrenches may be fully immersed. Rinse soap from wrenches under warm running water for a minimum of 1 minute to clear soap residue.

8.1.8. Dry all components with absorbent towel or paper. Dispose of cloth or paper in accordance with Hospital or Clinic practices for contaminated wastes.

8.1.9 With a cloth or absorbent paper moistened with an anti-microbial and anti-viral cleaning agent, wipe down the Handpiece Cable, Generator, Irrigation Unit (if supplied) and Aspiration Unit (if supplied). Clean all surfaces of bloodstains and obvious signs of contamination. Dispose of cloth or paper with contaminated wastes.

8.1.10 Examine the Probe, Handpiece, and Handpiece Cable for obvious signs of damage (cracks, gouges, cuts in Cable, etc.). Remove any items that show signs of damage from service **after** cleaning and sterilizing. Mark damaged items clearly to prevent future use before disposal.

CAUTION - DO NOT immerse the Handpiece Cable, Generator, Irrigation Unit, (if supplied) or the Aspiration Unit (if supplied). Units are not sealed against liquids and damage to equipment may result.

8.1.11 Probes, Handpiece, Front Cap, Handpiece Cable and Wrenches can be sterilized by steam autoclave. If autoclaving, place Handpiece, Probes and Cables in suitable sterilizer tray, such as LySonix Tray, part number 2010-30.

CAUTION – Allow time for all components to cool to room temperature before use

8.1.12 Sterilizing by Steam Autoclave:

8.1.12.1 Handpiece and Cap (with front cap removed):

121°C gravity 50 minutes wrapped or unwrapped
132°C gravity 10 minutes unwrapped, 20 minutes wrapped
PREVAC, 132°C 3 minutes wrapped or unwrapped

8.1.12.2 Cannulated Probes:

121°C gravity 60 minutes wrapped or unwrapped
132°C gravity 30 minutes wrapped or unwrapped
PREVAC, 132°C 5 minutes wrapped or unwrapped

8.1.12.3 Cable:

121°C gravity 50 minutes wrapped or unwrapped
132°C gravity 10 minutes unwrapped, 20 minutes wrapped
PREVAC, 132°C 3 minutes wrapped or unwrapped

8.1.13 Dry cycle: **MINIMUM** of 5 minutes is recommended.

8.2 Reuse Life of Components

8.2.1 The estimated reuse life of system components is listed below. All reuse life estimates are approximate and may be affected by rough handling, damage, and wear due to vigorous cleaning, etc.

Component	Reuse Life (Number of sterilization cycles)
Handpiece	200 cycles
Handpiece Cable	200 cycles
Front Cap	200 cycles
All Probes	>200 cycles
Wrenches	>200 cycles

NOTE: - The Reuse Life given takes into account wear and tear due to cleaning and sterilization only. Damage or wear caused by actual use in surgery will affect life of components.

8.3 Deviations from Cleaning and Sterilization Instructions

8.3.1 It is highly recommended that the procedures given in this manual for cleaning and sterilizing the LySonix 3000® with PulseSelect™ and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilization if they differ from the procedures as outlined in this manual.

8.4 Technical Assistance

8.4.1. Should the user wish further information or instructions regarding any aspect of cleaning or sterilizing procedures, please contact;

Byron Medical, Inc.
602 West Rillito Street
Tucson, Arizona 85705
(800) 777-3434 (Toll Free)
(520) 573-0857 (outside USA)
(520) 746-1757 (Fax)

9. SERVICE, REPAIR and TECHNICAL CORRESPONDENCE

WARNING: To avoid electric shock DO NOT remove the case cover from the Generator, the irrigation and aspiration units, or the handpiece. There are no user-serviceable parts inside any of these components.

9.1. Fuse Replacement

9.1.1. Switch Mains Switch to OFF. Switch Ultrasound Enable Switch to OFF.

9.1.2. Unplug Power Cord from both wall outlet and the Generator. Use a small screwdriver to remove the fuse holder below the Power Cord connector by releasing the spring-loaded snap connectors.

9.1.3. Pull out the fuse holder.

9.1.4. Remove and replace with new fuses of the same type as installed. There is no required orientation of the fuses. Be certain to replace both fuses.

9.1.5. Reinstall the fuse holder by pressing it into the power connector until it snaps in place.

9.1.6. Reattach Power Cord to both rear panel connector and wall socket. Switch Main Switch to ON. Continue to test unit as instructed in Section 4.

WARNING: If after fuse replacement and the fuse fails when the generator is reactivated, discontinue use of the device and contact Byron Medical, Inc., immediately.

9.2. Repair Service and Replacement Parts

9.2.1. If repairs are necessary due to damage other than that incurred during initial shipment (see section labeled DAMAGE OR LOSS IN SHIPMENT), contact Byron Medical (800) 777-3434 or (520) 573-0857 to return your unit. A Return Goods Authorization number must be obtained from Byron Medical's Customer Service Department prior to returning any merchandise. When requesting a Return Goods Authorization number, please follow the return policy as listed under the section labeled POLICY ON RETURNED GOODS. Then, please carefully repack and return it post-paid to:

Byron Medical, Inc.
Attn: Repairs Department
RGA #:_____
602 West Rillito Street
Tucson, Arizona 85705

9.2.2. Repairs must be made by Byron Medical or by an approved authorized agent. Attempting repair without prior authorization nullifies all warranties.

9.3. Modifications

9.3.1. Modifications of any kind are NOT recommended and will void all warranties.

9.4. Damage or Loss in Shipment

9.4.1. Thoroughly inspect shipment immediately upon arrival. If goods are received short or in damaged condition, it is important that you notify the transportation company and insist on a notation of the loss or damage on the freight bill. Otherwise, it may be difficult to make a claim against the transportation Company.

9.4.2. If concealed loss or damage is discovered, retain all packaging materials, notify the transportation company immediately, and request an inspection. The agent will make an inspection and grant a concealed damage notation. A concealed damage report must be made within seven (7) days of shipment delivery. After seven (7) days, the transportation company reserves the right to refuse any claim for loss or damage.

9.5. Incorrect Items Shipped by Byron Medical

9.5.1. Please check your shipment immediately for any shortage or incorrect items. If any discrepancies exist, notify Byron Medical, (520) 573-0857 or 1-800-777-3434, at once. Your prompt attention will ensure credit or exchange.

9.5.2. ALL DISCREPANCIES BETWEEN THE PACKING LIST AND THE PRODUCTS RECEIVED MUST BE REPORTED WITHIN 48 HOURS OF RECEIPT OF THE PACKAGE TO QUALIFY FOR A CREDIT.

9.6. Policy on Returned Goods

CAUTION: USE ONLY APPROVED SHIPPING MATERIALS AND BOXES. USE OF UNAPPROVED SHIPPING MATERIALS CAN RESULT IN ADDITIONAL DAMAGE AND VOID WARRANTIES.

9.6.1. NO RETURNS OR EXCHANGES WILL BE ACCEPTED UNLESS YOU HAVE RECEIVED A RETURN OF GOODS AUTHORIZATION NUMBER (RGA) FROM BYRON MEDICAL. THIS NUMBER MUST BE ON THE RETURN BOX AND ALL WRITTEN COMMUNICATION.

9.6.2. Return numbers will expire if items are not returned within 30 days.

9.6.3. Credit will only be issued if the merchandise is in saleable condition. If the product has been used in surgery, the product must be CLEANED WITH A DISINFECTANT and a written statement confirming such must accompany the product(s).

9.6.4. Full credit will be issued for any item returned in 30 days that is in undamaged and saleable condition.

9.6.5. A restocking charge of 25% will be charged to any product returned between 31-90 days. A credit memo, based on the dollar amount, will be issued to the account.

9.6.6. OPENED PACKAGES OR BOXES containing disposable items are not returnable for credit or exchange. Each package or sales unit specifically states **"Not Returnable if Package Seal is Broken."**

9.6.7. NO CREDIT WILL BE ISSUED ON ANY ITEM RETURNED AFTER 90 DAYS.

9.6.8. CREDIT MEMOS EXPIRE TWO YEARS AFTER DATE OF ISSUE.

Manufacturer:
Misonix, Inc.
1938 New Highway
Farmingdale, New York 11735
(631) 694-9555
(800) 645-9846

Distributor:
Byron Medical, Inc.
602 West Rillito Street
Tucson, Arizona 85705
(520) 573-0857
(800) 777-3434

EU Representative:
Labcaire Systems Ltd
175 Keen Road
Clevedon, North Somerset BS216
England

BYRON MEDICAL LIMITED WARRANTY

Byron Medical warrants each LySonix® product distributed by it to be free from defects in material and workmanship under normal use and service from the period(s) and components set forth below. Byron Medical's obligation under this warranty is limited to the repair or replacement, at its sole option, or any product, or part thereof, which has been returned within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses to Byron Medical's contracted factory in a way so as in Byron medical's judgment, to affect stability or reliability, or which has been subjected to misuse, neglect or accident. Shipping this product without proper packaging materials or failing to use proper packing procedures in Byron Medical's judgment may void this warranty.

Because Byron medical has no control over the conditions of use, patient selection, surgical procedure, post surgical course or handling of the device after it leaves our possession, Byron Medical does not warrant either a good effect or against an ill effect following use. Byron Medical shall not be responsible for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this product.

This warranty is in lieu of all other warranties, expressed, or implied, including without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of Byron Medical. Byron medical neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any Byron Medical Products. Not withstanding any other provision herein or in any other document or communication, Byron medical's ability with respect to this aggregate purchase price for the goods sold by Byron Medical to the Customer. There are no warranties, which extend beyond the terms hereof. Byron medical disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

This warranty and the rights of obligations hereunder shall be construed under the laws governed by the State of Arizona, USA. The sole forum for resolving disputes arising under or relating in any way to this warranty is the District Court for the County of Pima, State of Arizona.

Byron Medical, its dealers and representatives, reserve the right to make changes in equipment built and/or sold by them at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.

Use of replacement products other than those recommended by Byron Medical may void the warranty herein described.

The warranty period for the LySonix® Ultrasonic Surgical System components are as follows:

Electrosurgical Generator:	
-2000 Model	One year from date of shipment
-3000 Model	One year from date of shipment
-Refurbished model	Six months from date of shipment
Operating Handpiece(s)	
-Standard	Six months from date of shipment
-Micro FineLine	Six months from date of shipment
-Refurbished	Three months from date of shipment
Umbilical Cables	Six months from date of shipment
Footswitches (all models)	One year from date of shipment
Ultrasonic Probes	Six months from date of shipment (These disposable components are warranteed against defects in workmanship for their useful life).

Distributed by:

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602 West Rillito Street
Tucson, Arizona 85705
(520) 573-0857

Printed in the USA

Reference Misonix Part # E5000AML30